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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/990,243	<b>Applicant(s)</b> PHILLIPS, JONATHAN	
	<b>Examiner</b> Pedro Philogene	<b>Art Unit</b> 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 4/22/04.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7,8,23, 26,29,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis, Jr. et al (5,354,305).

With respect to claims 1 and 26, Lewis discloses in FIG.3-5, a device comprising an elongated member (10) having a longitudinal axis, a proximal and distal end sections (around 4) and a solid central section (around 12) extending between the proximal and distal fastener receiving areas (14) of greater solid cross-sectional dimensions than the central section, the fastening receiving areas each having at least one hole (24) extending transverse to the longitudinal axis for receiving a cross fastener adapted to secure to the bone on opposite sides of the elongate member, the proximal and distal end sections thereby providing rigid anchoring locations relative to the central section, the central section providing flexibility, as set forth in column 4, line 26, to promote healing of a fracture. As for the preamble and the functional language limitations regarding the intramedullary nail and fixing a fracture of a long bone, the Lewis device is biocompatible; as set forth in column 4, line 25, and is inherently capable of functioning as a nail; as best seen in FIGS 7-9. Additionally applicant's specification discusses the diameter of the central section being, in general, between 4-7 mm (p. 11, line 20). Lewis discloses in column 4, lines 18-24 a preferable dimension of the device being slightly

smaller at about 0.05 inch (about 1.27 mm). As such, the Lewis device is disclosed as inherently capable of at least fixing a fracture of a long bone of a smaller human or animal.

Also regarding the limitation "of greater cross-sectional dimension" in claims 1 and 26 and consistent with page 12, lines 2-7 of applicant's specification discussing the width as a cross sectional dimension, figure 3 shows the cross-sectional width dimension of the end sections is greater than the width dimension of the central section.

With respect to claims 7,8 21, 23, 29,30, Lewis discloses all the limitations; as set forth in column 4, lines 25,26; and, as best seen in FIGS3-5.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, Jr. et al. (5,354,305).

With respect to claim 6, it is noted that Lewis did not teach of a device having a ratio of the fastening areas between 1.3:1, as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach such a ratio, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 2-5, 9, 21, 22, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, Jr. et al. (5,354,305) in view of Faccioli et al. (5,620,449).

With respect to claims 2-5,9,21,22,27, 28, it is noted that Lewis did not teach of a central section that is malleable to allow bending; as claimed by applicant. However, in a similar art, Faccioli et al. column 3, lines 35-61, column 6, lines 55-65, evidence the use of a bending nail, as taught by applicant, to provide adjustable axial position of the intramedullary nail.

Therefore, given the teaching of Faccioli et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Lewis, as taught by Faccioli et al. to provide adjustable axial position of the intramedullary nail.

As to the material of nail, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use any known material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 16,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, Jr. et al. (5,354,305) in view of Faccioli et al. (5,620,449) in view of Sterghos (4,788,847).

With respect to claims 16,17, it is noted that the above combination of references did teach of a bending device, but fail to teach of a bending device having jaw structure;

as claimed by applicant. However, in a similar art, Sterghos, evidences the use of a bending device having jaw structure to effect the bending of a rod.

Therefore, given the teaching of Sterghos, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the bending device of Faccioli with the bending device of Sterghos to effect the bending of the intramedullary nail.

Claims 10-15, 24,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faccioli et al. (5,620,449) in view of Lewis, Jr. et al. (5,354,305).

With respect to claims 10-15, 24,25, it is noted that Faccioli et al disclose all the method steps, as set forth; except for proximal and distal fastener receiving areas of greater dimension relative the cross sectional dimension of the central section. However, in a similar art, Lewis evidences the use of a nail with a solid cross section and proximal and distal fastener receiving areas of greater dimension relative the cross sectional dimension of the central section to allow the implant to be more easily inserted longitudinally.

Therefore, given the teaching of Lewis, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the shape of the implant of Lewis in the device of Facciloi et al to allow the implant to be more easily inserted longitudinally.

### ***Response to Arguments***

In response to applicant's arguments, the recitation an intramedullary nail for insertion within an intramedullary canal of a long bone has not been given patentable

weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant's arguments with respect to claims 2-6,9-17,21,22,24,25,27-29 have been considered but are moot in view of the new ground(s) of rejection.

### **Conclusion**

A shortened statutory period for reply to this action is set to expire **THREE MONTHS** from the mailing date of this action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene  
August 06, 2004

  
PEDRO PHILOGENE  
PRIMARY EXAMINER